

**REMARKS**

Claims 18-20 are all the claims pending in the application and claims 18-20 are currently rejected.

In this Amendment Applicants cancel claims 18-20 and add claims 21-23.

Claims 21-23 include a step of determining whether IL-12 is induced in a patient. Such is supported by the specification in Examples 1-8 and Tables 1-4, showing the determination of IL-12 levels in patients. Methods for measuring IL-12 levels in serum are well known in the art.

Claims 21-23 include a step of continuing to administer the compound(s) of step (a). Support may be found in the specification at page 12, stating that compounds of the present invention can induce IL-12, and that administering such compositions to induce IL-12 is a method to cure cancer. Therefore, once IL-12 induction is confirmed, the IL-12 inducing drug is continually administered to cure the cancer. Support can also be found in Example 1, page 13, stating that an IL-12 inducing composition was “continually administered” until the tumor had completely disappeared.

Applicants submit corrected Tables 1-4, and replace the 2<sup>nd</sup> full paragraph on page 13. The original Tables had a typographical error in the unit of IL-12, which should be pg/ml and not ng/ml. Support for a pg/ml unit is found in the specification as filed. For example, the third paragraph on page 13 and the last paragraph on page 14 both describe the correct unit of serum IL-12 as pg/ml. In addition, one skilled in the art would have known the correct unit for serum IL-12, and would have recognized that ng/ml was 1000-fold too high, and thus, clearly a typographical error.

Accordingly, Applicants assert that no new matter has been added and respectfully request entry of the amendment.

Rejections Under 35 U.S.C. § 102(b)

The Examiner rejects claim 18 as anticipated by *Ghoneum et al.*, Int. J. Immunotherapy 11(1):23-28 (1995) (Ghoneum I) and *Ghoneum*, Natural Immunity 13(4):228 (1994) (Ghoneum II). Specifically, the Examiner contends that since Ghoneum I and II disclose administering AHCC to patients, claim 18 is anticipated.

Applicants cancel claim 18 and add claim 21. Claim 21 includes a step for determining whether IL-12 is induced in said patient, and includes a step for continuing to administer IL-12 to said patient. Since neither Ghoneum I nor II teach determining IL-12 levels after administering AHCC, or teach continuing to administer AHCC based on IL-12 induction, neither Ghoneum I or II anticipate claim 21.

Accordingly, Applicants request entry of the Amendment, and respectfully request that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 103

(1) The Examiner rejects claim 19 as obvious over Ghoneum I or Ghoneum II in view of *Fujii et al.* (U.S. Patent 4,207,312). Specifically, the Examiner contends that Ghoneum I and II disclose administration of AHCC to cancer patients and Fujii discloses anticancer activity of

fungal mycelia. The Examiner asserts that it is *prima facie* obvious to combine two or more ingredients for a purpose where each has been taught individually for that purpose.

Applicants cancel claim 19 and add claim 22. Claim 22 includes a step for determining whether IL-12 is induced in said patient, and includes a step for continuing to administer IL-12 to said patient. Since neither Ghoneum I or II, nor Fujii, teach determining IL-12 levels after administering AHCC and components of fungal mycelia, or teach continuing to administer AHCC and fungal mycelia based on IL-12 induction, claim 22 is not obvious over Ghoneum I or II in view of Fujii.

Accordingly, Applicants request entry of the Amendment, and respectfully request that this rejection be withdrawn.

(2) The Examiner rejects claim 20 as obvious over Ghoneum I or Ghoneum II in view of *Fujii et al.* (U.S. Patent 4,207,312), and in further view of *Sugawara et al.* (U.S. Patent 4,242,326). Specifically, the Examiner contends that Ghoneum I and II disclose administration of AHCC to cancer patients, Fujii discloses anticancer activity of fungal mycelia, and Sugawara discloses that hemolytic streptococci are useful as anti-cancer agents. The Examiner asserts that it is *prima facie* obvious to combine two or more ingredients for a purpose where each has been taught individually for that purpose.

Applicants cancel claim 20 and add claim 22. Claim 22 includes a step for determining whether IL-12 is induced in said patient, and includes a step for continuing to administer IL-12 to said patient. Since neither Ghoneum I or II, Fujii, or Sugawara teach determining IL-12 levels after administering AHCC, components of fungal mycelia, and components of hemolytic

streptococci- or teach continuing to administer AHCC, components of fungal mycelia, and components of hemolytic streptococci based on IL-12 induction- claim 22 is not obvious over Ghoneum I or II in view of Fujii, and further in view of Sugawara.

Accordingly, Applicants request entry of the Amendment, and respectfully request that this rejection be withdrawn.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Mark L. Hayman  
Registration No. 51,793

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE  
**23373**  
CUSTOMER NUMBER

Date: January 7, 2004